REMARKS

By this amendment, claims 30 and 35-37 are amended, and new claims 45-47 are added. There are now 41 claims pending. These are 1-5, 7-12, 15-19, 22-31 and 33-47. No new matter is introduced by the amendments or new claims and support for the amendments is found throughout the specification. The new claims are combinations of matter encompassed by the previously pending claims and further recite specific conditions (Claims 45-47) or menopausal or postmenopausal women (Claim 44) who are administered the vitamin composition. This response and amendment is timely filed in response to the Office Action mailed on June 29, 2005.

Applicant's representative thanks Examiner Henry and Examiner Barts for extending the courtesy of an interview on September 7, 2005.

Claim Objections

Claims 35-37 were objected to because of an informality which has been overcome by inserting the word "acid" after the word "folic".

Rejection of Claims Under 35 U.S.C. § 112 (first paragraph)

Claims 1-5, 7-12, 15-19, 22-31 and 33-43 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner stated that the specification does not support use of the words "consisting of." The claims, as pending, are supported by the specification on page 10, first paragraph. Applicant respectfully asserts that the rejection under 35 U.S.C. § 112, first paragraph, has been overcome and requests its withdrawal.

The Examiner asserts that the use of the term "calcium" means that none of the compounds or derivatives of calcium can be used in the claimed composition. Applicant respectfully asserts that the definition of "calcium" on page 5 indicates that the term "calcium" is used herein to refer to any form of calcium including calcium carbonate, phosphate, lactate, gluconate, citrate and combinations thereof. Accordingly, the use of the word "calcium" in the claims includes these forms of calcium.

Rejection of Claims Under 35 U.S.C. § 112 (second paragraph)

Claims 15-19, 22, 24, 30, 33 and 41-43 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject which applicant regards as the invention. The

Examiner asserted that the phrase "a condition associated with a hormonal change" in claims 15, 24 and 41-43, renders the claims indefinite. More specifically, the Examiner asserts that it is unclear what condition(s) are associated with a hormonal change and how this or these condition(s) must be related to the hormonal change to be considered as being associated with the hormonal change.

Applicant respectfully asserts that these terms are completely defined on pages 13 and 14 of the specification.

> "As used herein, the term "hormonal change" refers to any increase or decrease in a hormone within an individual and the term "condition" refers to any disease, illness, infection, or potentially detrimental change in the health of an individual. A condition "associated" with a hormonal change can be directly or indirectly caused by the hormonal change. Conditions associated with hormonal changes include, but are not limited to, conditions associated with menopause, hormone replacement therapy, ovariectomy/hysterectomy, cancer therapy, hot flashes, bone loss, high-risk pregnancy, osteoporosis, endometriosis, and uterine fibroids. "Treatment of" or "treating" a condition does not require elimination of the condition, i.e., curing of a disease."

Further, on pages 14 and 15, Applicant further describes various conditions including, but not limited to, hot flashes, high-risk pregnancy, osteoporosis, endometriosis, uterine fibroids, hyperhomocystineamia, bone loss, "in-situ" vascular free radical formation and hypertension, osteoporosis, cardiovascular disease, and osteopenia. On these pages Applicant describes treating individuals including those who have undergone or are undergoing treatment with cancer chemotherapy, estrogen, androgen, estrogen-androgen combination therapies, progesterone, estrogen-progesterone combination therapies or other steroids; are or were smokers; or are experiencing or have experienced menopause or ovariectomy/hysterectomy.

In view of this extensive disclosure in the specification, Applicant asserts that the claims are not indefinite, the conditions are clearly stated, and that one of ordinary skill in the art would be able to practice the invention, as claimed. Applicant requests withdrawal of the rejection of claims 15-19, 22, 24, 30, 33 and 41-43 under 35 U.S.C. § 112, second paragraph,

Rejection of Claims Under 35 U.S.C. § 103

Claims 1-5, 7-12, 31 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (U.S. Patent No. 5,494,678, hereinafter Paradissis) in view of MedicineNet.com. For the record, Applicant's undersigned attorney requested verification of the date of the MedicineNet.com reference. The Examiner has confirmed to Applicant's attorney that the correct year of this reference is 1999 and not 1995. Applicant requests confirmation of this date by the Examiner.

The Examiner asserts that Paradissis discloses a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6, and vitamin B1. The Examiner asserts that MedicineNet.com discloses that childbearing women and adults should take a multivitamin composition containing 400 mcg folic acid, 2-3 mg of vitamin B6, 6-9 mcg of vitamin B12, and 400 IU of vitamin D. The Examiner asserts that it would have been obvious to one of ordinary skill in the art in view of Paradissis and MedicineNet.com to do the following: a) to make Paradissis's composition for pregnant women; 2) to exclude vitamin B1 from Paradissis's composition; and, 3) to use any amount or quantity of the components. The Examiner further asserts that MedicineNet.com discloses that vitamin B1 is not required in said composition and that amounts or quantities of components used in a composition depends on factors such as the severity of the condition and the mass of the individual.

Applicant respectfully traverses this rejection. Applicant is not making Paradissis's composition for pregnant women. Applicant's composition is different from that disclosed in Paradissis or in MedicineNet.com. Applicant respectfully asserts that one of ordinary skill in the art would not be motivated by reading MedicineNet.com to delete an ingredient in Paradissis's composition in order to derive Applicant's claimed composition. MedicineNet.com does not disclose, teach or suggest that vitamin B1 is not required in Paradissis's composition. MedicineNet.com is completely silent regarding vitamin B1. Since MedicineNet.com is completely silent regarding vitamin B1, MedicineNet.com does not suggest or provide motivation to one of ordinary skill in the art to delete vitamin B1 from Paradissis's composition.

MedicineNet.com discusses vitamin D deficiency in the elderly (page 1, paragraph 1). Next MedicineNet.com provides some general guidelines about prevention of neural tube defects in children through increased consumption of folic acid in women of childbearing age, and provides general guidelines about vitamin toxicity (page 2), and vitamin deficiencies (pages 3 and 4). The Examiner asserts that MedicineNet.com discloses that childbearing women and adults should take a multivitamin composition containing 400 mcg folic acid, 2-3 mg of vitamin B6, 6-9 mcg of vitamin B12, and 400 IU of vitamin D. In fact, MedicineNet.com actually discloses the following on page 1 in the section entitled "What are some general guidelines from *MedicineNet.com* based on available data?":

> "Adults should take one multivitamin daily. One multivitamin a day is safe and inexpensive. The multivitamin should contain 400 micrograms of folic acid, approximately 2-3 mg of vitamin B6, 6-9 micrograms of vitamin of B12, and 400 IU of vitamin D."

Applicant respectfully asserts that this statement is a general statement concerning adults and is not directed to women of childbearing years. In fact, only the statement concerning folic acid and neural tube defects in MedicineNet.com is directed to women in childbearing years. Accordingly, Applicant respectfully asserts that the statement in MedicineNet.com is taken out of context with regard to women of childbearing years and should not be combined with Paradissis et al. One of ordinary skill in the art reading this general statement in MedicineNet.com would not be motivated to combine it with Paradissis which is concerned with specific supplements for pregnant women in different trimesters of pregnancy. Further, since this combination of references is inappropriate with regard to women of childbearing years, one of skill in the art would not be motivated to delete an ingredient (vitamin B1) from the composition of Paradissis. There is no motivation or suggestion in MedicineNet.com to delete an ingredient (vitamin B1) from Paradissis to prepare the composition of Paradissis, in contrast to the Examiner's assertion on page 5, paragraph 2. Paradissis includes vitamin B1 in every single disclosed embodiment. Deletion of vitamin B1 from every embodiment disclosed by Paradissis could render these compositions of Paradissis unsatisfactory for their intended purpose or change their principle of operation, as supplements to be administered during the different trimesters of pregnancy. Paradissis includes B1 in each specific formulation for each trimester and varies the amount of B1 depending on the use in each trimester.

In contrast to the Examiner's assertion on page 5, paragraph 2, Applicant is not preparing the composition of Paradissis, but has claimed a different composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6. Vitamin B1 is not in Applicant's composition, as claimed. Further, there is no motivation or suggestion in MedicineNet.com to delete an ingredient (vitamin B1) from Paradissis to prepare the composition claimed by Applicant. The cited prior art does not suggest the desirability of the combination claimed by Applicant consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6.

Applicant's claimed composition is effective. Applicant conducted a study concerning administration of one embodiment of the present invention to post menopausal women. This embodiment consisted of folic acid (1.6 mg), vitamin B12 (425 mcg), vitamin B6 (25 mg) B6, vitamin D (400 IU) and calcium (400 mg), administered in two pills per day. Plasma homocysteine levels were measured before and six weeks after administration of the vitamin composition. The results show greater than a 20% reduction in plasma homocysteine levels in the postmenopausal women receiving the vitamin. These striking and unexpected results demonstrate the remarkable efficacy of Applicant's claimed vitamin composition. The cited art, alone or in combination, does not teach, suggest or provide motivation to make Applicant's composition, as claimed, which is efficacious at least in post-menopausal women to reduce homocysteine levels.

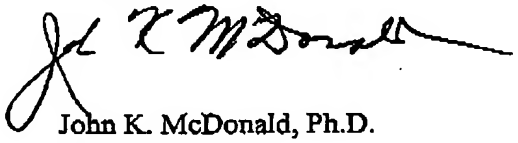
For at least all of the reasons cited above, Applicant respectfully asserts that the rejection of claims 1-5, 7-12, 31 and 34 under 35 U.S.C. § 103(a) has been overcome and requests its withdrawal.

CONCLUSION

Applicant submits that the pending claims define novel and patentable subject matter. Accordingly, Applicant respectfully requests allowance of these claims. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required, or credit any overpayment, to Deposit Account Number 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes any informalities remain in the application that can be resolved by telephone interview, a telephone call to the undersigned attorney is earnestly solicited.

Respectfully submitted,



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